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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,381	04/17/2001	Mikiko Suga	206018US0	5139

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/835,381

Applicant(s)
Suga et al.

Examiner
Christian L. Fronda

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/2003 (Paper No.11) has been entered.
2. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
4. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.
Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21, as written, do not sufficiently distinguish over nucleic acids, proteins, and/or cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "transformed" or "recombinant". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any coryneform bacteria having any “nucleotide sequence with a degree of homology that it can homologously recombine” with the nucleotide sequence of SEQ ID NO: 17 or any “nucleotide sequence with a degree of homology that it can homologously recombine” with any nucleotide sequence which encodes the amino acid sequence of SEQ ID NO: 18. However, the specification discloses only a single representative species encompassed by these claims: a *Brevibacterium lactofermentum* strain containing a disruption of the *argR* gene, wherein said *argR* gene consists of the nucleotide sequence of SEQ ID NO: 17 and said strain is identified as strain AJ13029ΔR. There is no written description for the specific regions or degree of homology for the nucleotide sequence of SEQ ID NO: 17 or any nucleotide sequence which encodes the amino acid sequence of SEQ ID NO: 18 from which any nucleotide sequence can recombine with. The specification also fails to describe additional representative species of coryneform bacteria encompassed by the claims by any identifying structural characteristics or properties other than the strain AJ13029ΔR having a disruption in the *argR* gene consisting of the nucleotide sequence of SEQ ID NO: 17 which encodes the arginine repressor for which no predictability of structure is apparent.

Given the lack of additional representative species, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

7. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a *Brevibacterium lactofermentum* strain containing a disruption of the *argR* gene, wherein said *argR* gene consists of the nucleotide sequence of SEQ ID NO: 17 and said strain is identified as strain AJ13029ΔR, does not reasonably provide enablement for any coryneform bacterium having any polynucleotide having any degree of homology to SEQ ID NO: 17 or polynucleotide encoding SEQ ID NO: 18 that it should cause homologous recombination. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

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The nature and breadth of the claims encompass any coryneform bacterium having any polynucleotide having any degree of homology to SEQ ID NO: 17 or polynucleotide encoding SEQ ID NO: 18 that it should cause homologous recombination. The specification provides guidance and examples in making a *Brevibacterium lactofermentum* strain containing a disruption of the *argR* gene, wherein said *argR* gene consists of the nucleotide sequence of SEQ ID NO: 17 and said strain is identified as strain AJ13029ΔR.

While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific coryneform bacterium having any *argR* gene that has a nucleotide or amino acid sequence having any degree of homology to SEQ ID NO: 17 or SEQ ID NO: 18 that it should cause homologous recombination is lacking. Thus, searching for such coryneform bacterium is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to determine the specific coryneform bacterium having any *argR* gene that has a nucleotide or amino acid sequence having any degree of homology to SEQ ID NO: 17 or SEQ ID NO: 18 that it should cause homologous recombination is enormous. Such experimentation entails selecting a species of coryneform bacteria out of a vast number of species, isolating the arginine repressor from the selected species, obtaining the amino acid sequence of the isolated arginine repressor, and determining if it has any degree of homology to SEQ ID NO: 17 or SEQ ID NO: 18 that it should cause homologous recombination.

Since routine experimentation in the art does not include the enormous amount of experimentation stated above where the expectation of obtaining the desired species of coryneform bacteria is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as the nucleotide sequence of the gene encoding the arginine repressor having any degree of homology to SEQ ID NO: 17 or SEQ ID NO: 18 that it should cause homologous recombination. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 2, the phrase "has a nucleotide sequence with a degree of homology that it can homologously recombine" renders the claims vague and indefinite because the specific degree of homology is not known and not recited in the claim and the entire meaning of the phrase is not known. Claims 6, 9, 12, 15, and 18, and 20 which depend from claim 2 are also rejected because they do not correct the defect of claim 2

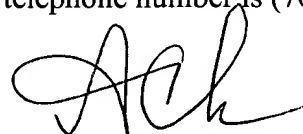
In claim 3, the phrase "with a degree of homology that it can homologously recombine" renders the claim indefinite because the specific degree of homology is not known and not recited in the claim and the entire meaning of the phrase is not known. Claims 7, 10, 13, 16, 19, and 21 which depend from claim 3 are also rejected because they do not correct the defect of claim 3.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF


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